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10/527,561	03/11/2005	Ihor E. Kopka	21204P	7320

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EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/527,561	KOPKA ET AL.	
	Examiner	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-17 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment, which included cancellation of claims 10, 18-23, addition of new claim 24 and amendment to claim 8, filed on 3/11/2005 is made of record. Claims 1-9, 11-17 and 24 are now pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following apply. Any claim not specifically rejected is rejected as it dependent on a rejected claim and shares the same indefiniteness.

1. Recitation of "and pharmaceutically acceptable salts thereof" in claim 2-9 and 24, renders these claims indefinite as it is not clear whether these claims are compound claim or composition claim with above said limitations. Note Markush recitation should be in alternate form and in singular.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-16 are rejected under U.S.C. 112, first paragraph, because the specification while being enabling for treating obesity, does not reasonably provide enablement for treating any disease or disorder mediated by cannabinoid (CB-1),

receptor. The specification does not enable any physician skilled in the art of medicine, to use the invention commensurate in scope with these claims. The factors to be considered in making an enablement rejection have been summarized above.

The instant claims 11-16 are drawn to treating a cannabinoid receptor mediated disease by inhibiting the activity of cannabinoid receptor in general or CB-1 receptor in specific.. The scope of the claims includes any or all diseases and disorders due to cannabinoid receptor inhibition activity including those yet to be discovered as due said mode of action for which there is no enabling disclosure. In addition, the scope of these claims includes treatment of various diseases, which is not adequately enabled solely based on the activity of the compounds provided in the specification at pages 1-2 and 156-157. The instant compounds are disclosed to have cannabinoid receptor inhibitory activity and it is recited that the instant compounds are therefore useful in treating any or all diseases stated above for which applicants provide no competent evidence. It appears that the applicants are asserting that the embraced compounds because of their mode action as cannabinoid receptor inhibitor that would be useful for all sorts of diseases and disorders , including, psychosis, memory deficit, cognitive disorders, migraine, neuropathy, neuroinflammatory disorders including multiple sclerosis and Guillain-Barre syndrome and the inflammatory sequelae of viral encephalitis, cerebral vascular accident, and head trauma anxiety disorders, stress, epilepsy, Parkinson's disease, movement disorders, and schizophrenia, substance abuse disorders, eating disorders, constipation and chronic intestinal pseudo-obstruction, as well as for the treatment of asthma, and cirrhosis of the liver.

However, the applicants have not provided any competent evidence that the instantly disclosed tests are highly predictive for all the uses disclosed and embraced by the claim language for the intended host. Moreover many if not most of diseases such as Alzheimer's disease Parkinson's disease, cancers , autoimmune diseases are very difficult to treat and despite the fact that there are many drugs, which can be used for "inflammatory condition".

The scope of the claim16 includes not only treating but also "preventing obesity " which is not adequately enabled solely based on the activity of the compounds as inhibitors of cannabinoid-1 receptor activity provided in the specification.

"To prevent" actually means to anticipate or counter in advance, to keep from happening etc. (as per Websters II Dictionary) and there is no disclosure as to how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the "prevention" effect. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein.

The scope of the claims involves all of the thousands of compounds of claim 1 as well as the thousand of diseases embraced by the terms a disease or disorder and cancer,

Cancer is just an umbrella term. Tumors vary from those so benign that they are never treated to those so virulent that all present therapy is useless.

No compound has ever been found to treat any or all diseases and disorders and cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "compound" is contrary to our present understanding of oncology. Cecil Textbook of Medicine states, "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study" (see the enclosed article, page 1004). Different types of cancers affect different organs and have different methods of growth and harm to the body. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally. Note substantiation of utility and its scope is required when utility is "speculative", "sufficiently unusual" or not provided. See Ex parte Jovanovics, 211 USPQ 907, 909; In re Langer 183 USPQ 288. Also note Hoffman v. Klaus 9 USPQ 2d 1657 and Ex parte Powers 220 USPQ 925 regarding type of testing needed to support in vivo uses.

Next, applicant's attention is drawn to the Revised Utility and Written Description Guidelines, at 66 FR 1092-1099, 2001 wherein it is emphasized that 'a claimed invention must have a specific and substantial utility'. The disclosure in the instant case is not sufficient to enable the instantly claimed method treating solely based on the inhibitory activity disclosed for the compounds. The state of the art is indicative of the requirement for undue experimentation. See Petrocellis et al., British Journal of Pharmacology, 141, 765-774, 2004, especially the concluding paragraph.. See also Black, Curr. Opin.. Investig. Drugs 5(4): 389-394, 2004 (PubMed Abstract provided)

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1) The nature of the invention: Therapeutic use of the compounds in treating disorders/diseases that require cannabinoid receptor inhibitory activity.

2) The state of the prior art: Recent publications expressed that the cannabinoid receptor inhibition effects are unpredictable and are still exploratory. See references cited above.

3) The predictability or lack thereof in the art: Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for r treating any or all condition of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

4) The amount of direction or guidance present and 5) the presence or absence of working examples: Specification has no working examples to show treating any or all condition and the state of the art is that the effects of cannabinoid receptor inhibitors are unpredictable.

6) The breadth of the claims: The instant claims embrace any or all diseases or disorders and cancers including those yet to be related to cannabinoid receptor activity.
7) The quantity of experimentation needed would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the pharmaceutical use, for the reasons stated above.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of enzyme-inhibitor interactions in general, and the lack of working examples regarding the activity of the claimed compounds towards treating the variety of diseases of the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

MPEP §2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was 'filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Agarwal et al., WO 2004/009560.

Agarwal et al. teaches several substituted pyrimidine compounds useful as cyclooxgenase inhibitors for treating pain and other diseases, which include instant compound generically claimed in the instant claims. See page 9, formula I and note the definition of A, R1, R2, R3, R4, R5 and R6. Note with a given A choice, when R5 and R6 are either aryl or heteroaryl, compounds taught by Agarwal et al. include instant compounds. See entire document, especially pages 13-17 for various substituted pyrimidine compounds. Particularly see page 16, species on line 9-11, 13, 14 and 18. See also examples 7 through 15, pages 33-37, wherein the starting material uracils are also claimed in the instant claims.

Claims 1-8,11, 12 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Akahane et al., WO 2004/016605.

Akahane et al. teaches several 2-aminopyrimidine compounds useful for treating dementia and depression, which include instant compound generically claimed in the instant claims. See page 4, formula I and note the definition of R^1, R^2, R^3, R^4 and R^5. Note with a given R^3 choices, compounds taught by Akahane et al. include instant compound. See entire document for details of the invention, especially pages 5-12 for various process of making aminosubstituted pyrimidine compounds. Particularly see pages 38-48 , for examples 1 through 27 of compounds made

Claims 1-8 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Agarwal et al., WO 03/084935.

Agarwal et al. teaches several diaryl pyrimidine compounds useful as cyclooxgenase inhibitors for treating pain and other diseases, which include instant compound generically claimed in the instant claims. See page 9, formula I and note the definition of A, B, R1, R2, R3, R4, R5, R6, R7 and R8. Note with a given A and B choices, when R5 and R6 form a double bond, compounds taught by Agarwal et al. include instant compounds. See entire document, especially pages 14-15 for various substituted pyrimidine compounds which include several compounds claimed in the instant claims. See page 38-47, examples 5-20 for compounds made.

Claims 1-8,11,12 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsutsumi et al. US 2005/0043315.

Tsutsumi et al. teaches several aminopyrimidine compounds useful for treating dementia and depression, which include instant compound generically claimed in the instant claims. See page 1, formula I and note the definition of Q, R^1, R^2 and R^3. Note

with a given Q choices, compounds taught by Tsutsumi et al. include instant compound. See entire document for details of the invention, especially pages 3-7 for various process of making aminosubstituted pyrimidine compounds. Particularly see pages 30-69, examples 1 through 253 for compounds made.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Spohr et al., US 6,096,753.

Spohr et al. teaches several substituted pyrimidine compounds, for treating pain and other diseases, which include the intermediates of these compounds claimed in the instant claims. See column 2, formula 1 and note the definition of various variable groups. Especially note when the core is pyrimidine of formula shown on column 5, line 5, R_{11} and R_{12} is aryl or heteroaryl, compounds taught by Spohr et al. include instant compounds. See entire document for details. Especially see compounds shown in Table spanning column 21 through 43. Note compounds these compounds were made form the corresponding N-unsutituted pyrimiidine. See examples 1-57,column 61-122, all of which show N-alkyl pyrimidine made form the corresponding N-unsubstituted pyrimiidine.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Cherkofsky US 4,438,117.

Cherkofsky teaches several 2-substitutedthio-4,5-diarylpyrimidine compounds, for treating arthritis, which include compounds claimed in the instant claims. See column 1, formula shown inline 45 and note the definition of R_1, R_2, R_3 groups. Especially note when R_1 and R_1 is aryl or pyridyl, compounds taught by Cherkofsky

include instant compounds. See entire document for details. See column 3-4 for examples 1-15 for compounds made.

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Olivera et al., Tetrahedron 58(15): 3021-3037, 2002.

Olivera teaches several 2,6-unsubstitutedt-4,5-diarylpyrimidine compounds, which include compounds claimed in the instant claims. See entire document especially see 3022-3024 for various 4,5-diarylcompounds.

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al., Gaodeng Xuexiao Huaxue Xuebao 16(11): 1740-1743, 1995. CA 124: 317095,1996. CAPLUS Abstract provided.

Huang teaches several pyrimidine compounds, which include compounds claimed in the instant claims. See entire CAPLUS Abstract for various pyrimidine compounds.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al., DD 294255, CA 116: 128952,1992. CAPLUS Abstract provided.

Fischer teaches several pyrimidine compounds, which include compounds claimed in the instant claims. See entire CAPLUS Abstract for various pyrimidine compounds.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Khilya et al., Chemistry of Natural Compounds (Translation of Khimya Prirodnykh Soedinenii) 37(4): 307-310, 2001, CA 137: 78805, 2002. CAPLUS Abstract provided.

Khilya teaches several pyrimidine compounds, which include compounds claimed in the instant claims. See entire CAPLUS Abstract for various pyrimidine compounds.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Khilya et al., Khimya Geterotsiklicheskikh Soedinenii, 11: 1542-1550, 1985, CA 105: 208819, 1986. CAPLUS Abstract provided.

Khilya teaches several pyrimidine compounds, which include compounds claimed in the instant claims. See entire CAPLUS Abstract for various pyrimidine compounds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agarwal et al., WO 2004/009560.

Teachings of Agarwal et al. as discussed in the above 102 rejection is incorporated herein. As noted above, Agarwal et al. teaches several substituted pyrimidine compounds useful as cyclooxgenase inhibitors for treating pain and other diseases, which include instant compound generically claimed in the instant claims.

Agarwal et al. differs from the instant claims in exemplifying only some of the compounds embraced in the genus of compound of formula I shown in page 9.

However, Agarwal et al. teaches equivalency of those compounds taught in pages 16, and 33-37 with those generically recited in pages 9-10.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Agarwal et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-9, 11, 12,17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akahane et al., WO 2004/016605.

Teachings of Akahane et al. as discussed in the above 102 rejection is incorporated herein. As noted above, Akahane et al. teaches several aminopyrimidine compounds useful for treating dementia and depression, which include instant compound generically claimed in the instant claims.

Akahane et al. differs from the instant claims in exemplifying only some of the compounds embraced in the genus of compound of formula I shown in page 4.

However, Akahane et al. teaches equivalency of those compounds taught in pages 38-48, examples 1-27 with those generically recited for formula I in page 4.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Akahane et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-9, 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agarwal et al., WO 03/084935.

Teachings of Agarwal et al. as discussed in the above 102 rejection is incorporated herein. As noted above, Agarwal et al. teaches several substituted pyrimidine compounds useful as cyclooxgenase inhibitors for treating pain and other diseases, which include instant compound generically claimed in the instant claims.

Agarwal et al. differs from the instant claims in exemplifying only some of the compounds embraced in the genus of compound of formula I shown in page 9.

However, Agarwal et al. teaches equivalency of those compounds taught in page 38-47, examples 5-20, with those generically recited in pages 9-10.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Agarwal et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-9, 11, 12,17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsutsumi et al. US 2005/0043315.

Teachings of Tsutsumi et al. as discussed in the above 102 rejection is incorporated herein. As noted above, Akahane et al. teaches several aminopyrimidine compounds useful for treating dementia and depression, which include instant compound generically claimed in the instant claims.

Tsutsumi et al. differs from the instant claims in exemplifying only some of the compounds embraced in the genus of compound of formula I shown in page 1.

However, Tsutsumi et al. teaches equivalency of those compounds taught in pages 30-69, examples 1-253 with those generically recited for formula I in page 1.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Tsutsumi et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from

8.00 AM to 6.00 PM. The Acting Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

Venkataraman Balasubramanian

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9/2/2005